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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,013	12/24/2001	Rosann Kaylor	KCX-461 (15790)	1072

7590 02/03/2009

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ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/035,013
Filing Date: December 24, 2001
Appellant(s): KAYLOR ET AL.

Mr. Jason Johnston
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/21/08 appealing from the Office action mailed 4/18/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

NEW GROUND(S) OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeSimone et al. (either EP 0308770 or USP 4,833,088).

Both Desimone et al. references are substantially identical in their teachings as applied to the instant rejections. Additionally, both DeSimone et al. references use the same element numbers so that each referenced element is from both references. To avoid redundancy, the Office will only make specific reference to the USP reference.

These references teach a reflectance photometer system(10) that receives a test strip(24) which further comprises reagent pad(22). DeSimone et al. teach in the USP 4,833,088 column 3 lines 17-25 ambient light is blocked from the read head during measurement of the reagent pad by an elastomeric light seal(70). Column 7 line 37 teaches the seal(70) is preferably a silicone rubber. The Office has interpreted the seal(70) which blocks ambient light from the read head as also performing the converse

function of absorbing all stray light from the electromagnetic radiation generated within the chamber during analysis. Additionally, the instant claim language is sufficiently broad in "absorbing" (e.g. no specific amount of absorption is required), that one having ordinary skill in the art would have expected any non-reflective material, such as silicone rubber, would inherently absorb some portion of light and meet the instant claim language.

The claimed *"lateral flow membrane strip"* has been read on the taught **test strip(24).** The claimed *"reading device comprising a housing ... "* has been read on the taught **reflectance photometer system(10).** The claimed *"light barrier structure comprising a top plate and a bottom plate ... the aperture having a size that approximates the size of the detection zone"* has been read on the taught **light seal(78/76)** and **aperture plate(166)** respectively. The claimed *"light absorbing member"* has been read on the taught **elastomeric seal(70).**

DeSimone teaches a rectangular aperture(176) in figure 10 and is silent to the claimed "*circular*" aperture.

It is well known to apply simple substitution of one known element for another to obtain predictable and results. It is well known that an aperture can be in different shapes such as rectangular and circular. The choice of an aperture shape would have the well known and predictable results of permitting the desired exposure through the aperature. A circular aperture would have also been desirable to exclude the corners of the test pad that may not have uniformly absorbed the sample. It would have been desirable to simply substitute a

circular aperture for the taught rectangular aperture to obtain the predictable results of the desired exposure of the sample to the analysis means and to also gain the above advantages of excluding the corners of the test pad that may not have uniformly absorbed the sample.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,833,088	DeSimone et al.	05-1989
EP 0308770	DeSimone et al.	03-1989

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 62-64, 66, 69-72 and 74-80 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DeSimone et al. (either EP 0308770 or USP 4,833,088).

Both Desimone et al. references are substantially identical in their teachings as applied to the instant rejections. Additionally, both DeSimone et al. references use the same element numbers so that each referenced element is from both references. To avoid redundancy, the Office will only make specific reference to the USP reference.

These references teach a reflectance photometer system(10) that receives a test strip(24) which further comprises reagent pad(22). DeSimone et al. teach in the USP 4,833,088 column 3 lines 17-25 ambient light is blocked from the read head during measurement of the reagent pad by an elastomeric light seal(70). Column 7 line 37 teaches the seal(70) is preferably a silicone rubber. The Office has interpreted the seal(70) which blocks ambient light from the read head as also performing the converse function of absorbing all stray light from the electromagnetic radiation generated within the chamber during analysis. Additionally, the instant claim language is sufficiently broad in "absorbing" (e.g. no specific amount of absorption is required), that one having ordinary skill in the art would have expected any non-reflective material, such as silicone rubber, would inherently absorb some portion of light and meet the instant claim language.

The claimed *"lateral flow membrane strip"* has been read on the taught **test strip(24).** The claimed *"reading device comprising a housing …"* has been read on the taught **reflectance photometer system(10).** The claimed *"light barrier structure comprising a top plate and a bottom plate … the aperture having a size that approximates the size of the detection zone"* has been read on the taught **light seal(78/ 76)** and **aperture plate(166)** respectively**.** The claimed *"light absorbing member"* has been read on the taught **elastomeric seal(70).**

(10) Response to Argument

Appellant argues in section "I.A." on pages 5-7, DeSimone fails to teach the claimed "absorption pad." The Office maintains DeSimone teaches seal(70) that excludes ambient light and conversely would inherently absorb any stray light from within the chamber. Appellant further state DeSimone teaches shield(78) that seals against ambient light, but does not shield "*an area under which the membrane strip is impacted by electromagnetic radiation*" as required by independent claim 62. The instant claim language is sufficiently broad to include the interpretation of the patent that the top or front of strip(24) is the side the reagent pad(22) is attached and the underside the strip is the side opposite reagent pad(22). Figure 5 teaches seal(70) is on the underside of strip(24) and has been properly read on the pending claims.

Appellant argues in section "I.B." on pages 7-8 that DeSimone fail to teach the claimed *"aperture has a size that approximates the size of the detection zone."* The Office maintains this claim language is sufficiently broad to have been properly read on an aperture that encompasses any portion of the detection zone. DeSimone teaches aperture(176) which encompasses a portion of the detection zone and has been properly read on the claimed *"aperture has a size that approximates the size of the detection zone."*

Appellant argues in section "II." on page 8 that DeSimone does not teach *"... a capture reagent ... configured to directly or indirectly bind to the analyte."* The Office maintains DeSimone teach in column 4 lines 64-67 the taught reagent strip detects

glucose from a whole blood sample and meets the limitations of a reagent that binds to the analyte and provide a proportional colorimetric response.

Appellant argues in section "III." on page 8 that claim 72 requires the aperture to be *"elongated."* The Office maintains the instant language is sufficiently broad to have been properly read on the taught aperture(176) as illustrated in figure 10 that is elongated in the orientation parallel to surface(174).

Appellant argues in section "IV." on page 9 that DeSimone fails to anticipated under 35 USC 102(b) a circular aperture. The Office agrees and has made a new grounds of rejection that a circular aperture would have been obvious under 35 USC 103.

Appellant argues in section "V." on page 9 that DeSimone fails to teach a sample pad to which the sample is applied and a wicking pad in fluid communication with the strip. The Office maintains the blood sample is applied to reagent pad(22) on test strip(24). The Office also maintains the pad(22) is inherently bibulous and wicks/absorbs the blood sample. The Office maintains DeSimone meets the limitations of claims 79-80.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Gregory L Mills/
Supervisory Patent Examiner, Art Unit 1700

Conferees:

/Gregory L Mills/
Supervisory Patent Examiner, Art Unit 1700

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797